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6 c) determining if the individual has the genetic basis of
7 Gilbert's Syndrome, and

8 d) proceeding with the clinical drug trial based on the
9 knowledge of such individuals possessing or not possessing
10 the genetic basis of Gilbert's Syndrome.

1 3. (Three Times Amended) The method of claim 2 wherein the
2 sample contains DNA from the individual.

1 4. (Three Times Amended) The method of claim 2 wherein the
2 method further comprises a step:

3 eliminating individuals having the genetic basis of Gilbert's
4 Syndrome from the clinical drug trial.

1 5. (Three Times Amended) The method of claim 2 wherein the
2 method further comprises the step:

3 selecting individuals having the genetic basis for Gilbert's
4 Syndrome for the clinical drug trial.

1 6. (Three Times Amended) The method of claim 2 further
2 comprising:

3 e) interpreting the results of the clinical drug trial incorporating
4 data regarding the genetic basis of Gilbert's Syndrome in distinguishing adverse
5 effects of a drug.

1 7. (Three Times Amended) The method of claim 2 wherein
2 the method comprises the steps of:

- 3 a) isolating DNA from the sample,
4 b) amplifying a DNA region indicating the genetic basis for
5 Gilbert's Syndrome to form DNA fragments,
6 c) isolating the amplified DNA fragments, and
7 d) identifying individuals having the genetic basis of Gilbert's
8 Syndrome.

1 8. (Three Times Amended) The method of claim 7 wherein
2 step b) the DNA is amplified using a polymerase chain reaction (PCR) using a
3 radioactively labeled pair of nucleotide primers.

1 9. (Three Times Amended) The method of claim 7 wherein the
2 DNA region indicating the genetic basis of Gilbert's Syndrome is a gene
3 encoding UDP-glucuronosyltransferase (UGT).

1 10. (Three Times Amended) The method of claim 7 wherein the
2 DNA to be amplified is in an upstream promoter region of the UGT 1*1 exon 1.

1 11. (Three Times Amended) The method of claim 7 wherein the
2 DNA to be amplified includes a region between -35 and -55 nucleotides at the 5'
3 end of UGT 1*1 exon.

1 12. (Three Times Amended) A kit for screening participants for
2 clinical drug trials, wherein the kit comprises primers for amplifying a region of
3 DNA indicating a genetic basis of Gilbert's Syndrome, and the kit further
4 comprising instructions directing a user of the kit that the kit should be used to
5 identify drug trial participants having the genetic basis for Gilbert's Syndrome.

1 13. (Three Times Amended) Primers for use in amplifying the
2 DNA region in the method of claim 7, the primers comprising primer pairs, AB
3 or CD as follows:

4 A/B: (A,5' - AAGTGAAGTCCCTGCTACCTT-3' (SEQ ID NO:1),

5 B,5' -CCACTGGATCAACAGTATCT-3' (SEQ ID NO:2) or

6 C/D: (C,5' -GTCACGTGACACAGTCAAAC-3' (SEQ ID NO:3);

7 D 5' -TTTGCTCCTGCCAGAGGTT-3' (SEQ ID NO:4)).

Please add the following new claim:

1 14. (Newly Added) The method of claim 2 wherein the sample is
2 a blood sample or a buccal smear sample.